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**UNITED STATES DEPARTMENT OF COMMERCE
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AUG 22 1994

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,407,288 issued on October 4, 1983, was filed on August 16, 1994, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156(g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156(d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156. However, in view of the noted death of the inventor-assignee, it is apparent that Peter Forrest, the registered patent attorney who filed the application for patent term extension on behalf of the licensee-marketing applicant, did not have authorization to act on behalf of the beneficial owner of the patent, the Estate of Mieczyslaw Mirowski, at the time the application for patent term extension was filed.

C. E. Van Horn

Charles E. Van Horn
Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Peter Forrest
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